SPECIFIC PROVISIONS FOR THE ACCREDITATION OF CERTIFICATION BODIES IN THE FIELD OF MEDICAL DEVICES QUALITY MANAGEMENT SYSTEMS (ISO 13485)

Applicable from : 20.06.2022

DOCUMENT HISTORY

Revision and date of approval	Reason for revision	Impact of revision
0 **CC 22.01.2015**	New document - Formal integration of IAF MD 8:2015 and MD 9:2015 in the management system documentation of BELAC	
1 **Secr.** **18.05.2018**	Revision of IAF MD 8:2017 and IAF MD 9:2017 Revision of ISO/IEC 17021-1:2015 Revision of ISO 17011:2017	Full document
2 **CC correspondence ballot** **01.12.2020**	Revision of IAF MD 8:2020 Addition of the new regulatory framework that is and is being implemented based on decisions of the European Commission.	
3 **CC 26.04.2022**	Revision of IAF MD9:2022	Full document

SPECIFIC PROVISIONS FOR THE ACCREDITATION OF CERTIFICATION BODIES IN THE FIELD OF MEDICAL DEVICES QUALITY MANAGEMENT SYSTEMS (ISO 13485)

1. OBJECTIVES AND REFERENCES TO NORMATIVE DOCUMENTS

This document is intended to document the specific requirements and guidelines that shall apply for the accreditation of certification bodies in the field of medical devices quality management systems (ISO 13485)

It includes in particular :

- The specific requirements and guidelines related to the organization and operation of the certification body;
- The specific requirements and guidelines applicable to BELAC.

The specific requirements and guidelines for the direct performance of the conformity assessment activities are not detailed in the present document but a reference to the relevant documents is included.

The specific requirements and guidelines

- comply with the requirements of the document IAF MD 8:2020 and IAF MD 9:2022 ;
- are only endorsed when they comply with the general criteria documented in BELAC document 1-03 ;
- complement the requirements and guidelines that are in force to all BELAC accreditation activities.

2. RECIPIENTS

- Members of the Coordination Commission
- Members of the Accreditation Board
- Accreditation secretariat
- Assessors
- (Candidate) accredited bodies

3. DESCRIPTION OF THE ACTIVITY

3.1 Identification of the activity	**MDQS**
3.2 Type(s) of conformity assessment and accreditation standard	Certification of quality management system according to ISO 13485 • Accreditation according to EN ISO/IEC 17021-1:2015
3.3 Classification(s) according to BELAC 6-017	7.7
3.4 Reference document(s) for the activity ***(hereafter named "the scheme")*** , including the publication date or a version number	• ISO 13485:2016 • ISO 14971:2007 (until 17/12/2022) – ISO 14971:2019 • IAF MD 8:2020 (Application of ISO/IEC 17011:2017 in the field of Medical Device Quality Management Systems) • IAF MD 9:2022 (Application of ISO/IEC 17021-1 in the field of Medical Device Quality Management Systems) • Relevant documents from IMDRF (International Medical Device Regulatory Forum – www.imdrf.org)
3.5 Body responsible for the development and maintenance of the scheme ***(hereafter named « the scheme owner »)***	ISO EU (in case of certification within the framework of the relevant European Directives and Regulations)

4. SPECIFIC REQUIREMENTS APPLICABLE TO THE CONFORMITY ASSESSMENT BODY

During the accreditation assessments according to EN ISO/IEC 17021-1:2015 for certification against ISO 13485 or for conformity assessment activities provided by bodies notified in the framework of the relevant European harmonized Legislation, a specific evaluation is required to establish the compliance with the specific requirements listed hereafter; the relevant information will be included in the assessment report.

EN ISO/IEC 17021-1:2015	**Specific requirement of IAF MD 9:2022**
Clause 4.4 **Responsibility**	**MD.4.4.1** ISO 13485 requires the organization to comply with the statutory and regulatory requirements applicable to the safety and performance of the medical devices. The maintenance and evaluation of legal compliance is the responsibility of the client organization. The CAB is responsible for determining that the client organization has evaluated statutory and regulatory compliance and can show that appropriate action has been taken in cases of non-compliance with relevant legislation and regulations, including the notification to the Regulatory Authority of any incidences that require reporting.
Clause 5.1 **Legal and contractual matters**	**MD 5.1.2** The CAB shall establish appropriate agreements with their clients to release audit report information to regulators that recognize ISO 13485.
Clause 5.2 **Management of impartiality**	**MD 5.2.3** The CAB and its auditors shall be impartial and free from engagements and influences which could affect their objectivity, and in particular shall not be: a) involved in the design, manufacture, construction, marketing, installation, servicing or supply of the medical device, or any associated parts and services b) involved in the design, construction, implementation or maintenance of the quality management system being audited c) an authorized representative of the client organization, nor represent the parties engaged in these activities. The situations hereafter are examples where impartiality is compromised in reference to the criteria defined in a) to c): a) the auditor having a financial interest in the client organization being audited (e.g. holding stock in the organization)

	b) the auditor being employed currently by a manufacturer producing similar/competitive medical devices c) the auditor being a member of staff from a research or medical institute or a consultant having a commercial contract or equivalent interest with the manufacturer or manufacturers of similar medical devices.
Clause 7.1 **Competence of management and personnel**	**MD 7.1.1 Management and personnel competence** Where ISO/IEC 17021-1 Clause 7.1.1 refers to (as relevant for the specific certification scheme) ISO 13485, this should be understood to mean medical devices and applicable legal requirements. All personnel involved in ISO 13485 certification shall meet the competency requirements of Annex B.
Clause 7.2 **Personnel involved in the certification scheme**	**MD 7.2.4 Auditor** Each auditor shall have demonstrated competency as defined in Annex C. The CAB shall identify authorizations of its auditors using the Technical Areas in Tables in Annex A. **MD 7.2.5 Auditor experience** For a first authorization, the auditor shall comply with the following criteria, which shall be demonstrated in audits under guidance and supervision: a) has gained experience in the entire process of auditing medical device quality management systems, including review of documentation and risk management of applicable medical devices, parts or services (see Table A.1.7), implementation audit and audit reporting. b) Has gained experience by participation as a trainee in a minimum of four audits for a total of at least 20 days in an accredited QMS program, 50% of which shall be against ISO 13485 preferably in an accredited program, and the rest in any other accredited QMS program. In addition to criteria a), audit team leaders shall fulfil the following: a) has experience as an audit team leader role under the supervision of a qualified team leader for at least three ISO 13485 audits. **MD 7.2.8 Personnel making the certification decision** The CAB shall ensure that personnel (group or individual) making the certification decision fulfill the competence in Annex B. This does not mean that each individual in the group needs to comply with all requirements, but the group as a whole shall meet all the requirements.

	When the certification decision is made by an individual, the individual shall meet all the requirements.
Clause 8.1 **Public information**	**MD 8.1.3** Where it is required by law or by the relevant Regulatory Authority, the CAB shall provide the information about certifications granted, suspended or withdrawn to relevant Regulatory Authority.
Clause 8.2 **Certification documents**	**MD 8.2.1** The CAB shall precisely document the scope of certification. The CAB shall not exclude part of processes, products or services (unless allowed by regulatory authorities) from the scope of certification when those processes, products or services have an influence on the safety and quality of products.
Clause 9.1 **Pre-certification activities**	**MD 9.1.2.1** If the applicant organization uses outsourced processes, the CAB shall determine and document whether specific competence in the audit team is necessary to evaluate the control of the outsourced process. **MD 9.1.4 Determining audit time** The requirements from IAF Mandatory document MD5 (Determination of Audit Time of Quality, Environmental, and Occupational Health & Safety Management Systems) apply except those for EMS and OHSMS and the table QMS 1. Annex D, table D.1 replaces table QMS 1 and provides a starting point for estimating the audit time of an initial certification audit (Stage 1 + Stage 2). Audit time is dependent on factors such as the audit scope, objectives and specific regulatory requirements to be audited, as well on the range, class and complexity of medical devices, and the size and complexity of the organization. When CABs are planning audits, sufficient time shall be allowed for the audit team to determine the conformity status of the client organization's quality management system with respect to the relevant regulatory requirements. Time required to audit national or regional regulatory requirements and dossier reviews shall be additional and justified, so as not to diminish the audit time of the QMS. Audit time for all types of audits includes on-site time at a client's premises (physical or virtual) and time spent off-site carrying out planning, document review, interacting with client personnel and report writing. It does not consider the time required for design dossier reviews, type examinations, pre-market approval audits and other similar

	activities. The audit duration should be adjusted to take into account the factors listed in Annex D which may increase or decrease the estimated audit time. For those CAB's offering both ISO 9001 and ISO 13485 certification to a client, the audit time shall be able to demonstrate sufficient time to conduct an effective audit to determine conformity with all requirements of both certification standards. For information on ISO 9001 and ISO 13485 combined audits, see Annex D. For integrated audits for standards other than ISO 9001, see IAF MD11 **MD 9.1.5 Multi-site sampling** Sites involved in design, development and manufacturing of medical devices (Table A.1.1-1.6) cannot be sampled.
Clause 9.2 **Planning audits**	**MD 9.2.2.1** The audit team shall have the competence for the Technical Area (Annex A in conjunction with relevant knowledge and skills as defined in Annex B) for the scope of audit. If the audit is performed for an organization that only manufactures parts and offers services (see Table A.1.7), the audit team does not have to demonstrate technical competence at the same level as that for a manufacturer providing medical devices. To include devices that are sterile or intended for end-user sterilization, the audit team shall be competent according to sterilization process detailed in Table 1.5 of Annex A.
Clause 9.3 **Initial certification**	**MD 9.3.1** When a CAB has audited a client against a regulatory scheme that includes or goes beyond the requirements of ISO 13485, it does not need to repeat the audit for conformity with the elements of ISO 13485 previously covered, provided the CAB can demonstrate that all the requirements of this document have been complied with. Note: Some examples of regulatory schemes that include or go beyond the requirements of ISO13485 are European Medical Device Directives and Regulations. **MD 9.3.1.2 Stage 1** Where higher risk medical devices (e.g. GHTF C and D) are concerned, the stage 1 audit should be performed on-site.
Clause 9.4 **Conducting audits**	MD 9.4.5 Identifying and recording audit findings Examples of major nonconformities which require the acceptance and the verification of the effectiveness of correction and corrective actions are as follows: a) failure to fully address applicable requirements and implement an entire process for quality

	management systems (e.g. failure to have a complaint handling or training system) b) failure to implement applicable requirements for quality management systems c) failure to implement appropriate corrective and preventative action when an investigation of post market data indicates a pattern of product defects d) products which are put onto the market and cause undue risk to patient and/or users when the device is used according to the product labelling e) the existence of products which clearly do not comply with the client's specifications and/or the regulatory requirements f) repeated nonconformities from previous audits
Clause 9.6 **Maintaining certification**	**MD 9.6.2.2** In addition to requirements of Clause 9.6.2.2, the surveillance program shall include a review of actions taken for notification of adverse events, advisory notices, and recalls. **MD 9.6.4.2** Short notice or unannounced audits may be required when: i) external factors apply such as: a) devices in scope of certification indicate a possible significant deficiency in the quality management system b) significant safety and performance related information becoming known to the CAB ii) significant changes occur which have been submitted as required by the regulations or become known to the CAB, and which could affect the decision on the client's state of compliance with the regulatory requirements. iii) when required by legal requirements under public law or by the relevant Regulatory Authority. The following are examples of such changes which could be significant and relevant to the CAB when considering that a short notice or unannounced audit is required, although none of these changes should automatically trigger a short term or unannounced audit: i) <u>QMS – impact and changes</u>: a. New ownership b. Extension to manufacturing and/or design control c. New facility, site change • Modification of the site operation involved in the manufacturing activity (e.g. relocation of the manufacturing

	operation to a new site or centralizing the design and/or development functions for several manufacturing sites) d. new processes, process changes • Significant modifications to special processes (e.g. change in production from sterilization through a supplier to an on-site facility or a change in the method of sterilization) e. QM management, personnel • Modifications to the defined authority of the management representative that impact: ○ quality management system effectiveness or regulatory compliance ○ the capability and authority to assure that only safe and effective medical devices are released ii) <u>Product related changes</u>: a. New products, categories b. Addition of a new device category to the manufacturing scope within the quality management system (e.g. addition of sterile single use dialysis sets to an existing scope limited to haemodialysis equipment, or the addition of magnetic resonance imaging to an existing scope limited to ultrasound equipment) iii) <u>QMS & Product related changes</u>: a. Changes in standards, regulations b. Post market surveillance, vigilance An unannounced or short-notice audit may also be necessary if the CAB has justifiable concerns about implementation of corrective actions or compliance with standard and regulatory requirements.

5. SPECIFIC REQUIREMENTS APPLICABLE TO BELAC

The following table includes the specific requirements of IAF MD 8:2020 not explicitly covered by the general BELAC provisions for the accreditation of management systems certification bodies.

EN ISO/IEC 17011:2017 and/or ref to BELAC documents	**IAF MD 8:2020**	**Specific requirements**
Clause 4.4 Impartiality requirements	MD 4.4.5	Interested parties may include manufacturers or manufacturer associations, CABs, non-governmental organizations (NGOs), Regulatory Authorities or other organizations and users.
Clause 6.1 Competence of personnel BELAC 3-05 BELAC 3-09 BELAC 2-405-MDQS	MD 6.1.2	Normative Annex 2 specifies the type of knowledge and skills that the AB shall define for specific functions.
Clause /7.4 Preparation for assessment **BELAC 3-11**	MD 7.4.5	In the case of initial assessment, the samples for witnessing of audits shall include one audit minimum in a higher risk class Technical Areas in each Main Technical Area (shown in Annex 1) covered under the scope of accreditation, taking into account an appropriate national or international risk classification scheme and/or criticality of the process (e.g. Sterilization or Parts or Services). When developing a witnessing schedule, the Accreditation Body should consider, among other factors, the experience of the CAB e.g. recognized for one or more medical device regulatory scheme(s), in an effort to rationalize the witnessing schedule. Examples of typical regulatory schemes are: i. (EU) 2017/745/746 – European MDR/IVDR Regulations ii. ASEAN Medical Device Directive (AMDD) iii. National Medical Regulations that utilize ISO 13485 i.
Clause 7.6 Assessment	MD 7.6.4.1 MD 7.6.4.2	7.6.4.1 Prior to or during the assessment, the assessment team shall appraise publicly available information published by a sample

		of the certification body's certified manufacturers, including but not limited to websites, that advertise or otherwise promote the medical devices within the technical category that accredited ISO 13485 certification(s) have been issued for. 7.6.4.2 The appraisal shall be utilized during the on-site assessment activities to consider whether the technologies, intended purpose(s) and classification(s) of the medical devices as ascertained in audit reports and ISO 13485 certificates is consistent with the details of these ascertained from the publicly available information.
Clause 7.8 Accreditation information BELAC 3-11	MD 7.8.3 + Appendix 1	The accreditation certificate shall indicate the scope of accreditation which should clearly specify the Technical Areas as defined in Annex 1 – Scope of Accreditation.
Clause 7.9 Accreditation cycle BELAC 3-11	MD 7.11.2	The surveillance on-site office assessments shall be conducted at least once a year. Surveillance and reassessment shall include on-site assessment as well as witnessing. The witnessing program shall ensure, as a minimum, that one audit from each of the Main Technical Areas (shown in Annex A) under the scope of accreditation within an accreditation cycle (surveillances and/or reassessment) is conducted prior to the expiry of accreditation. The sampling for witnessing shall give priority to higher risk technical areas. Witness assessments should avoid the repeated witnessing of the same CAB client organization. The AB shall take into account previous results of witnessing to establish its witness strategy.
Clause 7.14 Records on conformity assessment bodies	MD 7.14.1	Records on the CAB shall include concerns, opinions and feedback received from a Regulatory Authority on the performance of the CAB pertaining to the scope of accreditation.
Clause 9.8 Management reviews	MD 9.8.2 MD 9.8.3	MD 9.8.2 Feedback from interested parties of clause 9.8.2 e) shall include any feedback received from Regulatory Authorities. MD 9.8.3

		Interested parties of clause 9.8.3 b) shall include Regulatory Authorities.

ANNEX A (IAF MD9)
(Normative)
Medical Devices Technical Areas

The CAB shall use the Technical Areas described in the tables of this Annex to:

a) help define the scope of certification

b) identify if any technical qualification, including competence in sterilization processes of its auditors is necessary for that particular technical area

c) select a suitably qualified audit team

When using technical areas other than specified in the tables, the technical areas shall be detailed.Main Technical Areas in Table 1.1 – 1.6 are applicable to finished medical devices.

Where the CAB applies for a scope of Accreditation for a technical area that has "other than specified above" in the description of technical area, the CAB shall provide a list of medical devices and include their risk classification to the AB.

The information provided shall also include a concise statement of the intended purpose of the medical device.

The technical area "Other than specified" may only be used when no other category is applicable. A risk classification of Medical Devices should be determined using appropriate regulatory sources. Examples include:

i. (EU) 2017/745 Annex VIII Classification Rules

ii. GHTF SG1 Principles of Medical Devices Classification GHTF/SG1/N77:2012

iii. National Classification Regulations (e.g., FDA)

Note: A finished medical device is defined as any device or accessory to any medical device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized.

Where the organization provides associated activitiesor manufacturing of parts which are not categorized as finished medical device, Table 1.7 shall be used for determining the scope.

To this end, the choice of provider to fall into the classification of the medical device must be supported by a decision of the RA and indicated in official Guidelines or Specifications issued to that purpose.

Table 1.1 - NON-ACTIVE MEDICAL DEVICES

Main Technical Areas	Technical Areas	Product Categories Covered by the Technical Areas
Non-active medical devices	General non-active, non-implantable medical devices	• Non-active devices for anesthesia, emergency and intensive care • Non-active devices for injection, infusion, transfusion and dialysis • Non-active orthopedic and rehabilitation devices • Non-active medical devices with measuring function • Non-active ophthalmologic devices • Non-active instruments • Contraceptive medical devices • Non-active medical devices for disinfecting, cleaning, rinsing • Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART) • Non-active medical devices for ingestion
	Non-active implants	• Non-active cardiovascular implants • Non-active orthopedic implants • Non-active functional implants • Non-active soft tissue implants
	Devices for wound care	• Bandages and wound dressings • Suture material and clamps • Other medical devices for wound • care
	Non-active dental devices and accessories	• Non-active dental • devices/equipment and instruments • Dental materials • Dental implants
	Non-active medical devices other than specified above	

Table 1.2 - ACTIVE (NON-IMPLANTABLE) MEDICAL DEVICES

Main Technical Areas	Technical Areas	Product Categories Covered by the Technical Areas
Active Medical Devices (non implantable)	General active medical devices	• Devices for extra-corporal circulation, infusion and haemopheresis • Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia • Devices for stimulation or inhibition • Active surgical devices • Active ophthalmologic devices • Active dental devices • Active devices for disinfection and sterilisation • Active rehabilitation devices and active prostheses • Active devices for patient positioning and transport • Active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART) • Software, including software design for medical devices • Medical gas supply systems and parts thereof
	Devices for imaging	• Devices utilizing ionizing radiation • Devices utilizing non-ionizing radiation
	Monitoring devices	• Monitoring devices of non-vital physiological parameters • Monitoring devices of vital physiological parameters
	Devices for radiation therapy and thermo therapy	• Devices utilising ionizing radiation • Devices utilising non-ionizing radiation • Devices for hyperthermia /hypothermia • Devices for (extracorporal) shockwave therapy (lithotripsy)
	Active (non-implantable) medical devices other than specified above	

Table 1.3 - ACTIVE IMPLANTABLE MEDICAL DEVICES

Main Technical Areas	Technical Areas	Product Categories Covered by the Technical Areas
Active implantable Medical Devices	General active implantable medical devices	• Active implantable medical devices for stimulation / inhibition • Active implantable medical devices delivering drugs or other substances • Active implantable medical devices substituting or replacing organ functions
	Implantable medical devices other than specified above	

Table 1.4 - IN VITRO DIAGNOSTIC MEDICAL DEVICES

Main Technical Areas	Technical Areas	Product Categories Covered by the Technical Areas
In Vitro Diagnostic Medical Devices (IVD)	Reagents and reagent products, calibrators and control materials for: • Clinical Chemistry • Immunochemistry (Immunology) • Haematology/Haemostasis/Immunohe ma-tology • Microbiology • Infectious Immunology • Histology/Cytology • Genetic Testing	
	IVD Instruments and software	
	IVD Medical devices other than specified above	

Table 1.5 – STERILIZATION METHODS FOR MEDICAL DEVICES

Main Technical Areas	Technical Areas	Product Categories Covered by the Technical Areas
Sterilization Method for Medical Devices	Ethylene oxide gas sterilization (EOG)	
	Moist heat	
	Aseptic processing	
	Radiation sterilization (e.g gamma, x-ray, electron beam)	
	Low temperature steam and formaldehyde sterilization	
	Thermic sterilization with dry heat	
	Sterilization with hydrogen peroxide	
	Sterilization method other than specified above	

Table 1.6 – DEVICES INCORPORATING / UTILIZING SPECIFIC SUBSTANCES /TECHNOLOGIES

Main Technical Areas	Technical Areas	Product Categories Covered by the Technical Areas
Devices incorporating/ utilizing specific substances / technologies	Medical devices incorporating medicinal substances	
	Medical devices utilizing tissues of animal origin	
	Medical devices incorporating derivates of human blood	
	Medical devices utilizing micromechanics	
	Medical devices utilizing nanomaterials	
	Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed	
	Medical devices incorporating or utilizing specific substances/technologies/elements other than specified above	

Table 1.7 PARTS AND SERVICES

Main Technical Areas	**Technical Areas**	**Product Categories Covered by the Technical Areas**
Parts or services	Raw materials	Raw metals, plastic, wood, ceramic
	Components	Electrical components, fasteners, shaped raw materials, machined raw materials and molded plastic
	Subassemblies	Electronic subassemblies mechanical subassemblies, made to drawings and/or work instructions
	Calibration services*	Verification/confirmation services for measuring instruments, tools or test fixtures
	Distribution services	Distributors providing storage and delivery of medical devices, not acting as a 'legal manufacturer' for medical devices.
	Maintenance services	Electrical or mechanical repair services, facility cleaning and maintenance services, uniform cleaning and testing of ESD smocks.
	Transportation services	Trucking, shipping, air transportation service in general.
	Other services	Consulting services related to medical devices, packaging services, etc.

*Organizations providing calibration services should be accredited to ISO/IEC 17025

Note: As for “Components, Subassemblies, Maintenance services, Other services (Consulting services related to medical devices)” listed in Main Technical Areas Table 1.7; the CAB shall be required to have accreditation of the scope of the technical areas listed in Table 1.1 - 1.6, when the degree of influence of organization’s part or services are clearly intended to support associated medical devices.

a) When an organization promotes itself or products as supporting a medical device in one of the main technical areas (e.g., fasteners marketed with a clear intent to support implanted medical devices) on their website; or

b) Instances of contract manufacturers making nearly complete medical devises

Annex B (IAF MD9)
(Normative)
Required types of knowledge and skills for personnel involved with the ISO 13485 activities

The following table specifies the type of knowledge and skills that a CAB shall define for
specific functions in addition to EN ISO/IEC 17021-1 Annex A.

Consideration for suppliers of "Parts and Services".
If the answer is "Yes" to any of the questions below, the audit team shall always include competence for the relevant Technical Areas in Tables A.1.1 – A.1.6 and the "Auditor" requirements in Table B.2. If the answer to all questions is "No", then the audit team shall satisfy only the "Parts and Services" auditor requirements in Table B.2. Documentation shall be maintained.

Table B.1

Question	Yes	No
Is the product a nearly finished medical device? (i.e., it is intended to be used for a medical purpose and only needs packaging and/or labeling)		
Is the product intended to be a component/part of a medical device?		
Is the organization contracted to carry out any activities that are regulated by a medical device regulation (e.g., relabeling, remanufacturing of other medical devices?		
Is the product supplied sterile?		
Does the product contain software developed by the client organization or a supplier?		
Is "Design and Development" in the scope of the ISO 13485 certification (e.g., when public law permits exclusion of design and development which is the case very often for low-risk medical devices)?		
Is the product (Raw Materials, Parts, Components, Subassemblies, Maintenance Services, or Other Services) intended to support associated medical devices? Note: refer to the note in Annex A, Table A.1.7, a) as an example		

Table B.2– Table of knowledge and skills

Certification functions / Knowledge and skills	Personnel conducting the application review to determine audit team competence required, to select the	Personnel reviewing audit reports and making certification decisions	Auditor	Parts and Services Auditor REF Table A.1.7	Personnel managing program

	audit team members, and to determine the audit duration				
Knowledge of generic quality management system practices	x	x	x	x	x
Knowledge of legal framework of regulations and role of the CAB	x	x	x	x	x
Knowledge of medical device risk management, e.g. ISO 14971	x	x	x	x	x
Knowledge of intended use of medical devices			x*		
Knowledge of risks associated with the medical device			x*		
Knowledge of relevant product standards in the assessment of medical devices			x*		
Knowledge of CAB's ISO 13485 processes	x	x	x	x	x
Knowledge of Medical Device business/technology	x	x	x*	x*	x

* The knowledge in the areas marked with * could be provided by a technical expert

Annex C (IAF MD9)
(Normative)
Auditor qualification, training and experience

C.1 Education

Except for auditors performing audits solely under Table A.1.7, the CAB shall ensure that auditors have the knowledge corresponding to post-secondary education (typically 4 years) or equivalent work experience. Appropriate professional areas are listed below as examples:

i) biology or microbiology;
ii) chemistry or biochemistry;
iii) computer and software technology;
iv) electrical, electronic, mechanical or bioengineering;
v) human physiology;
vi) medicine;
vii) pharmacy;
viii) physics or biophysics.

C.2 Work Experience

The CAB shall ensure that auditors have adequate experience to perform their tasks. In general, auditors shall have a minimum of four years of full-time work experience in the field of medical devices or related sectors (e.g. medical device industry, healthcare, medical device audit or research in medical devices).

Successful completion of other formal qualification (advanced degrees) can substitute for a maximum of two years of working experience.

Exceptionally, shorter duration of experience or experience in the fields other than medical devices or related sectors may be considered as appropriate. In such cases, the CAB shall demonstrate that the experience of the auditor is equivalent and shall record the justification for the acceptance.

Auditors performing audits of organizations solely under Table A.1.7 shall meet the requirements of ISO/IEC 17021-1 and ISO/IEC 17021-3 and not those in C2.

C.3 Auditor Competency

See Annex B.

C.4 Development and maintenance of competency

C.4.1 Continuous Professional Development (CPD)

Each auditor shall undertake a minimum of 8 hours of CPD activities per year such as training, participation in scientific meetings, and self-study for Table A.1.7 and a minimum of 16 hours of CPD for Tables A.1.1 – A.1.6. Such activities should ensure timely awareness of new or modified regulatory requirements,

policies, procedures, etc., as well as emerging technologies. Training in emerging technologies may be provided through co-operation with manufacturers developing or using the concepts. Knowledge is also gained from experience in enforcing regulatory requirements, implementing procedures, and applying policies and interpretations.

It is recognised that medical device manufacturing constitutes a highly specialized, technology driven and fast evolving sector. Additionally, new regulatory requirements, standards, policies, and procedures are introduced, and existing ones are modified from time to time. Therefore, the CAB shall ensure maintenance of the knowledge and skills of the auditors appropriate to cover the scope of audits of organizations, through appropriate and timely training and encouraging CPD.

C.4.2 Advanced training elements for auditors

As auditors gain competence in conducting audits, advanced and specialised training is recommended. The auditor's needs, weaknesses, and desires for career development may influence specific advanced training courses selected by an auditor. Subjects suggested for advanced training include:

i) Risk management, including risk analysis;
ii) Process validation;
iii) Sterilization and related processes;
iv) Electronics manufacture;
v) Plastics manufacturing processes;
vi) Development and validation of software or hardware for devices and manufacturing processes;
vii) In-depth knowledge of specific medical devices and/or technologies.

Annex D (IAF MD9)
(Normative)
Table D.1 – Determination of Audit Time (Initial Audit only)

Effective number of personnel	Audit duration Stage 1 + Stage 2 (days)	Effective number of personnel	Audit duration Stage 1 + Stage 2 (days)
1-5	3	**626-875**	15
6-10	4	**876-1175**	16
11-15	4,5	**1176-1550**	17
16-25	5	**1551-2025**	18
26-45	6	**2026-2675**	19
46-65	7	**2676-3450**	20
66-85	8	**3451-4350**	21
86-125	10	**4351-5450**	22
126-175	11	**5451-6800**	23
176-275	12	**6801-8500**	24
276-425	13	**8501-10700**	25
426-625	14	**>10700**	Follow progression above

Factors used to determine the audit time:

i) Some factors that may increase the audit duration from table D.1 are:

a. when more than one main technical area is required to be audited,
the audit time shall be increased to address any additional requirements related to the additional main technical area(s)

b. complexity of medical devices.

c. Manufacturers using suppliers to supply processes or parts that are critical to the function of the medical device and/or the safety of the user or finished products, including own label products. When the manufacturer cannot provide sufficient evidence for conformity with audit criteria, then additional time may be allowed for each supplier to be audited.

d. Manufacturers who install product on customer's premises. Note: Time may be required for customer site visits or installation records review

e. Poor regulatory compliance by the manufacturer

f. Multiple shifts, number of production lines etc. may increase audit duration

ii) Some factors that may reduce the audit duration but not by more than 20 % in total from table D.1 are

a. The organization's scope does not include manufacturing and is activities such as wholesale, retail, transportation or maintenance of equipment etc.

b. Reduction of the manufacturer product range since last audit
c. Reduction of the design/or production process since last audit

iii) Audit times performed solely for the certification scope of Distribution or transportation Services" may be reduced up to 50% in total from table D.1.

Conducting ISO 9001 and ISO 13485 Together
When determining the required time for conducting an ISO 9001 and ISO 13485 audit together, a minimum of 25% will be added to the minimum number of audit days calculated per Annex D. Conditions where additional time may be required include differences in scope, effective number of personnel, etc.
This applies whether the CAB is conducting an integrated audit or a combined audit.

ANNEX 2 (IAF MD8)
(Normative)
Required types of knowledge and skills for personnel involved with the ISO 13485 activities

The following table specifies the type of knowledge and skills that AB shall define for specific functions.

Accreditation functions / Knowledge and skills	Application review	Document review	Office assessment team	Witness assessment team	Reviewing assessment reports and making accreditation decisions	Administering program
Principles and applications of quality systems.		X	X	X	X	
Understanding of applicable GHTF SG4 and SG3 documents. (Being maintained by IMDRF)			X	X		
Understanding of ISO 13485			X	X	X (Note 1)	
Understanding of general regulatory requirements relevant to medical device manufacturers.			X	X	X (Note 1)	
Overview of medical devices, their intended use, safety and risks.			X	X		
The legal framework, including the regulatory requirements, their enforcement, and the role of the auditing organization.			X	X		
Information on CAB's client products, processes and organization to determine competence needed by the audit team and for the certification decision			X			
Information on CAB's processes						X

and organization to determine competence needed by the assessment team and for the accreditation decision						
Understanding CAB's client's products, processes and organization				X		
Ability to confirm that the CAB's processes are appropriate to support IAF ISO 13485 scheme.		X	X	X		
Ability to confirm that the CAB is competent to conduct a certification of the manufacturers, taking into account the processes and products involved.			X	X	X	
Ability to determine required appropriate duration of assessment.						X
Identification of medical devices including complexities, technologies, intended use and risk classifications.			X	X		
Deployment of assessor competences and requirements.						X
Knowledge on identifying and evaluating factors that impact an appropriate certification program for a medical device manufacturer seeking certification in a regulatory environment.			X	X		

Understanding of work performed at an accredited CAB.		X	X		X	X
Understanding of IAF Mandatory Documents for ISO 13485 scheme	X	X	X	X	X	X
Understanding of ISO/IEC 17021-1		X	X	X	X	X

NOTE 1: It is expected that the level of understanding for this activity would be less than that of an assessment team.
